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| EXAMINER | |
|---|---|
| KANTAMNENI, SHOBHA | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/590,301 | BABISH ET AL. | |
| | Examiner | Art Unit | |
| | Shobha Kantamneni | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-9 are pending and examined herein.

Applicant's amendment overcomes the rejection of claims 1, 4, and 7 under 35 U.S.C. 112, second paragraph, as being indefinite.

Applicant's arguments have been considered, but not found persuasive. The rejection of claims 1-3 under 35 U.S.C 102(e) as being anticipated by Shahlal et al. (US 6,583,322, PTO-1449) is MAINTAINED. See under response to arguments.

Applicant's arguments have been considered, but not found persuasive. The rejection of claims 1-9 under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2004/0137096, PTO-892) is MAINTAINED. See under response to arguments.

The rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 of copending Application No. 10/789,814 is MAINTAINED.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, and 8 are rejected under 35 U.S.C 102(e) as being anticipated by Shahlal et al. (US 6,583,322, PTO-1449).

Shahlal et al. discloses compositions comprising a reduced isoalpha acid (RIAA) and isoalpha acid (IAA). Isoalpha acids include isohumulone, isocohumulone, isoadhumulone, reduced isoalpha acid disclosed therein include dihydro isoalpha acids (DHIA), and hexahydro isoalpha acids ((HHIA). See abstract; FIG.1; FIG.2; column 1, lines 14-24.; lines 60-63; column 4, lines 2-25. It is also disclosed that compositions therein which are mixtures of DHIA, and IAA remained clear liquids at all ratios between about 1 and 99 %., and comprise at least 0.1 % of the composition. See column 18, lines 15-45. Shahlal also teaches that the RIAA, and IAA are derived from hops.

Thus, Shahlal et al. anticipates instant claims 1-3, and 8.

***Response to Arguments***

Applicant's arguments have been considered, but not found persuasive. Applicant argues that "Applicants submit that the range disclosed in Shahlal et al. does not fall within the ratios presently claimed and, therefore, Shahlal et al. cannot be an anticipatory reference." These arguments have been considered, but not found persuasive. Shahlal et al. discloses that high trans products of DHIA can be admixed with isoalpha acids and hexahydro isoalpha acids. See abstract; column 4, lines 21-23. It is also disclosed that compositions therein which are mixtures of DHIA, and IAA remained clear liquids at all ratios between about 1 and 99 %, and comprise at least 0.1 % of the composition. See column 18, lines 15-45. The ratios disclosed by Shahlal et al.

encompass/read on instant ratios of about 3:1 to about 1:10, and thus anticipate instant claims. Thus, Shahlal et al. anticipates instant claims 1-3, and 8.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2004/0137096, PTO-892).

Kuhrts teaches pharmaceutical compositions comprising hops extract consisting of iso-alpha acids (IAA), and reduced iso-alpha acids (RIAA) such as iso-humulone, iso-cohumulone, iso-adhumulone, dihydroiso-humulone, dihydroiso-adhumulone of the instant formula (Genus A), and combinations thereof. It is also disclosed that iso-alpha acids which are combinations of reduced isoalpha acid(RIAA) and isoalpha acid(IAA) will be present in an amount of 0.5 % to 10 % by weight in the hops extract. See page 4, paragraph [0027]; page [0031]; page 5, paragraph [0034], Example 1, wherein 3 % of Iso-alpha acids are present in the Hops extract; page 6, claims 1-5, 21-25.

Furthermore Kuhrts teaches the same method of reducing inflammation as instantly claimed, comprising administering Hops extract consisting of Iso-alpha acids and reduced iso-alpha acids such as iso-humulone, iso-cohumolone, iso-adhumolone,

dihydroiso-humolone, dihydroiso-adhumolone. See page 5, paragraphs [0035]-[0038] ; page 7, claims 1, 9,13, 21, 25.

Kuhrts does not expressly teach the ratio of reduced isoalpha acid : isoalpha acid as about 3:1 to about 1:10, in the composition.

Kuhrts does not expressly teach that the composition contains at least 0.1 % of RIAA and IAA individually.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid and isoalpha acid employed in the composition of Kuhrts, to obtain a desired effect such as reducing inflammation.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid and reduced isoalpha acid employed in the pharmaceutical compositions for methods of reducing inflammation in which the ratio of reduced isoalpha acid : isoalpha acid is about 3:1 to about 1:10, since the optimization of effective amounts of known agents to be administered , is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of Iso-alpha acid (IAA) and reduced isoalpha acid (RIAA) employed in the pharmaceutical compositions for methods of reducing inflammation as 0.1 % of RIAA and 0.1 % of IAA, since the optimization of effective amounts of known agents to be administered, is considered

well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Note: The ratio of RIAA to IAA of the instant claims such as 3:1 to 1:10 as in claim 1 is broad and might read on the ratio of the prior art composition, hops extract. The individual amounts of RIAA and IAA of the instant claims such as at least 0.1 % of the composition as in independent claims 1, 4, 7, includes any amount between 0.1 % to 99 % which is broad and might read on the prior art composition containing hops extract.

***Response to Arguments***

Applicant's argues that "Applicants describe in their application that "synergy was noted for all RIAA:IAA combinations, albeit at different segments of the dose-response curves." See Example 4 of the application as filed on page 31, paragraph 104 to page 32. This unexpected finding showed that while RIAA and IAA could act synergistically over a wide range of ratios and concentrations as shown in Figures 4A-H of the specification, they could also act additively or even antagonistically at certain other concentrations. See Figures 4A-H for tabulated CI (Combination Index) values and the specification on pages 30-31, paragraph [0100], which defines CI values of 1 to indicate synergism, additivity and antagonism, respectively." These remarks have been considered. It is pointed that synergy was noted at the higher end of the dose-response

curve for RIAA:IAA, ratios of 100:1, 3:1, 3:2, 2:3 and 1:10 over RIAA concentration of 0.31 to 68,261 µg/mL. No synergy was noted for a ratio of RIAA and IAA for example 1:1 wherein RIAA and IAA individually comprise at least 0.1 % of the composition. Thus, the evidence in the examples is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed method. See MPEP § 716.02(d). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art because Kuhrts teaches that the composition comprising iso-alpha acids such as iso-humulone, iso-cohumulone, iso-adhumulone, dihydroiso-humulone, dihydroiso-adhumulone of the instant formula (Genus A), and combinations thereof is useful in reducing inflammation.

Further, the ratio of RIAA to IAA of the instant claims such as 3:1 to 1:10 as in claims 1, 4, and 7 is broad and might read on the ratio of the prior art composition, hops extract. The individual amounts of RIAA and IAA of the instant claims such as at least 0.1 % of the composition as in independent claims 1, 4, 7, includes any amount between 0.1 % to 99 % which is broad and might read on the prior art composition containing hops extract.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 of copending Application No. 10/789,814. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims overlaps with the stated claims of 10/789,814. The instant claimed composition is within the scope of the claims of the copending Application 10/789,814. It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as the ratio of reduced isoalpha acid : isoalpha acid, to obtain a desired effect.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## *Conclusion*

No claims are allowed.

**THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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